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NICEATM

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March 31, 2006

Dr. William S. Stokes  
NICEATM Director  
NIEHS  
P.O. Box 12233  
MD EC-17  
Research Triangle Park, NC 27709

**RE: Nomination To Hold a Workshop on Alternative Methods to Replace the Mouse LD<sub>50</sub> Assay for Botulinum Toxin Potency Testing: Request for Comments, Nominations of Experts, and Submission of In Vivo and In Vitro Data, Federal Register, 71(18):4603, January 27, 2006.**

Dear Dr. Stokes:

Pursuant to the request from NICEATM and ICCVAM for information on activities directed at the development of alternatives the mouse LD<sub>50</sub> assay for botulinum toxin potency testing, I am providing the enclosed information.

Allergan supports the concept of a workshop to discuss alternative methods and approaches that might address the 3 R's for testing botulinum toxin for potency and product release. We have had internal R&D efforts focused on development and assessment of approaches to address each of the areas, reduction, refinement and replacement of the use of animals for botulinum potency testing for more than a decade. Significant progress has been achieved; however, the ultimate goal of replacement of the mouse LD<sub>50</sub> assay with a non-animal alternative assay has not yet been met. This remains a goal of the company with ongoing efforts focused on research on alternative assay methods.

ICCVAM has requested data from mouse LD<sub>50</sub> botulinum toxin potency testing and ex vivo and in vitro test methods used for potency testing. The types of data requested include raw data, protocols, test results and study reports. Unfortunately, because of the proprietary nature of that type of data, Allergan is not able to share it with the committee.

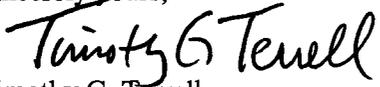
Allergan would like to support and contribute to the efforts by NICEATM and ICCVAM in the investigation of alternative test methods. Included with this submission are:

- Nominations of scientific experts who might participate in any future workshop
- **Selected Literature References**
- Compact Disc containing **electronic files** of all submitted material

As I mentioned in our discussion earlier this month, Allergan representatives including myself will be willing to give a presentation to the committee via webcast during your planning discussions if it is the wish of ICCVAM.

I will serve as the primary contact for future communications. In addition, I would most definitely like to participate in any future workshop on this topic should it occur. Correspondence can be sent by mail, fax or e-mail.

Sincerely yours,

  
Timothy G. Terrell

## NOMINATION OF SCIENTIFIC EXPERTS

Lance L. Simpson, PhD  
Professor of Medicine, Biochemistry and Molecular Pharmacology  
Thomas Jefferson University  
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K. Roger Aoki, PhD  
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Leonard Smith, PhD  
Chief, Department of Immunology and Molecular Biology  
Division of Toxinology and Aerobiology  
United States Army Medical Research Institute of Infectious  
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Prof. J. Oliver Dolly  
International Centre for Neurotherapeutics  
Research & Engineering Building  
Dublin City University  
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Eric A. Johnson, ScD  
Professor, Department of Food Microbiology & Toxicology  
Food Research Institute  
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